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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,915	03/19/2004	Lucian V. Di Pietro	A-846	9533
7590 12/21/2006 AMGEN INC. U.S. Patent Operations/JWB Dept. 4300, M/S 27-4-A One Amgen Center Drive Thousand Oaks, CA 91320-1799			EXAMINER ANDERSON, REBECCA L	
			ART UNIT	PAPER NUMBER
			1626	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		12/21/2006	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No. 10/804,915	Applicant(s) DI PIETRO ET AL.	
	Examiner Rebecca L. Anderson	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 22,23,26-29,39,41,42 and 51-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21,24,25,30-38,40 and 43-50 is/are rejected.
- 7) ☒ Claim(s) 1-21,24,25,30-38,40 and 43-50 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/1/04, 6/18/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-60 are currently pending in the instant application. Claims 22, 23, 26-28, 39, 41, 42 and 51-60 are withdrawn from consideration as being for non-elected subject matter. Claims 1-21, 24, 25, 30-38, 40 and 43-50 are objected and rejected.

Election/Restrictions

Applicant's election of Group I and the further election of example 259 in the reply filed on 18 October 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Therefore, based upon applicants' elected group and specific compound, as stated on pages 3 and 4 of the restriction requirement, **the elected invention for search and examination is:**

The products of the formula (III) wherein:

R₁" is H,

R₁ and R₁' are the same or different and are F, NO₂, CN, Cl, CHF₂, CF₃, -NR₇R₈ or -OR₉

wherein:

R is selected from a) or d);

R1a is substituted or unsubstituted 4-quinolyl and is optionally substituted as found in claim 45;

R2 is one or more substituents independently selected from H, halo, optionally substituted cycloalkyl, optionally substituted phenyl, cyano, alkylaminoalkoxy, nitro, and lower alkyl substituted with R6;

R3 is as found in claim 45; and

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R6 is one or more substituents independently selected from H, halo, optionally substituted cycloalkyl, optionally substituted phenyl, cyano, alkylaminoalkoxy and nitro

The remaining subject matter of claims 1-21, 24, 25, 30-38, 40 and 43-50 that is not drawn to the above elected invention and the subject matter of claims 22, 23, 26-28, 39, 41, 42 and 51-60 stands withdrawn under 37 CFR 1.142(b) as being for non elected subject matter. The remaining compounds which are not within the elected invention, which are independent and distinct from the elected invention and do not have unity with the species elected and therefore are withdrawn by means of a restriction requirement within the claim are, for example, the compounds wherein: R1a is 6-indazolyl, indolyl, isoindolyl, benzotriazolyl, quinazoliny; R is b) or c); R2 is -OR3, SR3, CO2R3; R6 is OR3, SR3, CO2R3, etc.

The above mentioned withdrawn compounds which are withdrawn from consideration as being for non elected subject matter differ materially in structure and composition from the compounds of the elected invention. The withdrawn compounds differ from those of the elected invention such as by, tetrazolyl, diazolyl, triazolyl, piperazine, piperidine, morpholine, etc. which are chemically recognized to differ in structure and function. This recognized chemical diversity of the compounds can be seen by the various classification of these compounds in the U.S. classification system, i.e. class 548 subclass 250+ (tetrazolyl), class 548 subclass 300.1+ (diazolyl), class 548 subclass 262.2+ (triazolyl), class 544 subclass 358+ (piperazine), class 544, subclasses 106(+) (morpholine), class 546 subclasses 184(+) (piperidine), etc. Therefore, again, the compounds which are withdrawn from consideration as being for non elected

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subject matter differ materially in structure and composition and have been restricted properly as a reference which anticipated but the elected subject matter would not even render obvious the non-elected subject matter. Nowhere do applicants argue to the contrary. Nowhere do applicants point out and give reasons why the claims do not involve independent or distinct subject matter. These withdrawn compounds are independent and distinct from the elected invention and do not have unity with the species elected and are therefore withdrawn by means of a restriction requirement within the claims.

Accordingly, restriction as has been presented in this application is proper.

Claim Objections

Claims 1-21, 24, 25, 30-38, 40 and 43-50 are objected to as containing non-elected subject matter. Claims 1-21, 24, 25, 30-38, 40 and 43-50 presented drawn solely to the elected invention as identified supra as the elected invention for search and examination would overcome this objection.

Claim 50 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must refer back to claims in the alternative. The phrase "any of claims 1-49 is not in the alternative". It is suggested that the phrase be amended to --any one of claims 1-49--. See MPEP § 608.01(n).

Claim 45 is objected to because of the following informalities: Specifically, while claim 45 has R1a attached to the formula III, line 22 of the claim on page 274 refers to "R1". The "R1" should be amended to "R1a". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21, 24, 25, 30-38, 40 and 43-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically these claims are drawn to products and "pharmaceutically acceptable derivatives thereof". The term "derivative" found in the claims is defined as a compound, usually organic obtained from another compound by a simple chemical process or a organic compound containing a structural radical similar to that from which it is derived (Hackh's chemical dictionary, 1972). Therefore, the term "derivative" found in the claims renders the claims indefinite because it is unclear what compounds are being claimed, i.e. what similar radical is found in the derivative and encompassed by the instant claims. It is suggested to overcome this rejection, applicant amend the claims to delete all instances of the term "derivative(s)" from the claims.

Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 45 defines the variable R4, however, there is no R4 present on Formula III which renders the claims indefinite as it is unclear where R4 is found on formula III.

Claims 1-21, 24, 25, 30-38, 40 and 43-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly

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claim the subject matter which applicant regards as the invention. Specifically, the claims contain one variable R2 which is variably attached to the compounds, however, the claims also state wherein "R2 is one or more substituents...". This renders the claims indefinite as it is unclear how one variable R2 is also more than one substituent and it is also unclear how many "more" R2 variables are present.

Claims 1-21, 24, 25, 30-38, 40 and 43-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claims include the term "contains" and "comprising". These statements render the claims indefinite since the terms are considered open ended which makes the scope of the products claimed impossible to determine. It is unclear what other atoms, substituents and functional groups are found in the variables and how and where these atoms, substituents and functional groups are connected. A claim to a chemical compound cannot be open-ended, but must be claimed with precision. This rejection can be overcome by deleting the term "comprising" and "contains" from the claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct

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from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 11-17, 19-21, 24, 30-34, 36-38, 40 and 43, 45, 46, and 48-50 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22 and 42 of copending Application No. 11/042,398. Although the conflicting claims are not identical, they are not patentably distinct from each other because conflicting claim 22 claims 5-(6,7-bis(methoxy)-4-quinolinyl)oxy)-N-(4-chlorophenyl)-1,3-benzoxazole-2-amine which anticipates applicants' claimed invention. Conflicting claim 42 is a pharmaceutical composition. The difference

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between the conflicting claims and applicants' elected invention is that the conflicting claims anticipate applicants' claimed invention. Therefore, the claims are provisionally rejected as obvious type double patenting since the conflicting claim 22 is claiming a species that is within applicants' claimed invention.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rebecca L. Anderson whose telephone number is (571) 272-0696. Mrs. Anderson can normally be reached Monday through Friday 5:30AM to 2:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

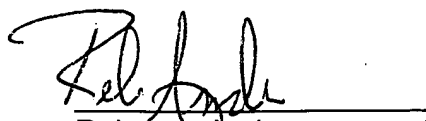
The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'Rebecca Anderson', written over a horizontal line.

Rebecca Anderson

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

December 19, 2006